



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0247]

Food and Drug Administration Transparency Initiative: Food and Drug Administration Report on Good Guidance Practices: Improving Efficiency and Transparency; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments.

SUMMARY: As part of the Transparency Initiative, the Food and Drug Administration (FDA or Agency) is announcing the availability of a report entitled "Food and Drug Administration Report on Good Guidance Practices: Improving Efficiency and Transparency." This report was prepared in response to Action Item 11 in the Phase III Report (FDA Transparency Initiative: Improving Transparency to Regulated Industry, dated January 2011). In that action item, the Commissioner of Food and Drugs (the Commissioner), Dr. Margaret A. Hamburg, called for a cross-Agency working group to prepare a report identifying FDA's "best practices" and making recommendations to streamline the development of guidance documents, reduce the time between issuing draft and final guidance documents, and make it easier to find guidance documents on FDA's Web site.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration,

5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets at the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

On January 21, 2009, President Obama issued a memorandum urging the heads of executive departments and Agencies to create an "unprecedented level of openness" to "strengthen our democracy and promote efficiency and effectiveness" (see Memorandum to Heads of Executive Departments and Agencies on Transparency and Open Government, January 21, 2009, (74 FR 4685, January 26, 2009)). In response, the following June FDA launched its Transparency Initiative. Information on the FDA Transparency Initiative is available at <http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/default.htm>.

As part of this initiative, FDA issued the Phase III Report (FDA Transparency Initiative: Improving Transparency to Regulated Industry, dated January 2011) in January 2011. The Phase III Report contained 19 action items and 5 draft proposals to make FDA's operations and decisionmaking processes more transparent and to foster more efficient and cost-effective regulatory processes. In Action Item 11 of the Phase III Report, the Commissioner called for a cross-Agency working group to prepare a report identifying FDA's "best practices" and making recommendations to: (1) Streamline the development of guidance documents, (2) reduce the time between issuing draft and final guidance documents, and (3) make it easier to find guidance documents on FDA's Web site.

In response to that action item, a cross-Agency working group under the leadership of the Office of Policy in the Office of the Commissioner prepared a report entitled "Food and Drug Administration Report on Good Guidance Practices: Improving Efficiency and Transparency" (GGP Report). The GGP Report identifies current "best practices" and recommends strategies to make the Agency's guidance processes more efficient and transparent. The cross-Agency working group submitted the GGP Report to the Commissioner on September 30, 2011.

These "best practices" and strategies are critical to the Agency because developing and issuing guidance documents is an enormous undertaking and one that is critical to fulfilling FDA's mission. In fiscal year (FY) 2009, the Agency issued approximately 124 guidance documents. Since that time, its issuance of guidance documents has been trending upward, with the Agency issuing approximately 133 guidance documents in FY 2010 and approximately 144 guidance documents in FY 2011. These numbers include draft and final Level 1 guidance documents and Level 2 guidance documents.

Guidance documents are prepared for FDA staff, the regulated industry, and/or the public and describe the Agency's interpretation of or policy on a regulatory issue (§ 10.115(b) (21 CFR 10.115(b)). Unlike statutes and regulations, guidance documents do not establish legally enforceable rights or responsibilities (§ 10.115(d)). There are two types of guidance documents: Level 1 and Level 2. Level 1 guidance documents are those that: (1) Set forth initial interpretations of statutory or regulatory requirements, (2) set forth changes in interpretation or policy that are of more than a minor nature, (3) include complex scientific issues, or (4) cover highly controversial issues (§ 10.115(c)). In contrast, Level 2 guidance documents set forth existing practices or minor changes in interpretation or policy. Level 2 guidance documents include all guidance documents that are not classified as Level 1 (see *id.*).

FDA's Good Guidance Practices regulation (§ 10.115) governs the development and issuance of guidance documents, and it gives interested persons a number of opportunities to provide input into the guidance document development process. Generally, FDA solicits public input on Level 1 guidance documents before implementation. The Agency posts draft Level 1 guidance documents on its Web site, and it publicizes them by issuing a Notice of Availability (NOA) in the Federal Register. Generally, the Agency accepts public comments on the guidance document for 60 days. In some instances, FDA may also hold public meetings or workshops on draft Level 1 guidance documents to solicit additional comments, or present the draft Level 1 guidance document to an advisory committee for review. Once the comment period has closed, the Agency reviews the comments and considers them as it prepares the final guidance document. The Agency also posts final Level 1 guidance documents on its Web site and publicizes them by issuing an NOA in the Federal Register.

Generally, FDA does not solicit public input on Level 2 guidance documents or on Level 1 guidance documents "for immediate implementation" (i.e., Level 1 guidance documents for which "prior public participation is not feasible or appropriate," § 10.115(g)(2)) before implementing the guidance document. However, FDA publishes an NOA in the Federal Register for Level 1 guidance "for immediate implementation" and posts both types of guidance documents on its Web site, and interested persons may comment on them at any time after they have been issued. FDA will review the comments and revise the guidance documents, as appropriate. This streamlined approach permits FDA to issue Level 1 guidance documents "for immediate implementation" and Level 2 guidance documents more expeditiously than standard Level 1 guidance documents, while still providing stakeholders with an opportunity to comment. Importantly, the additional administrative steps required for standard Level 1 guidance documents (i.e., issuing a draft guidance document, providing a comment period, and issuing a final guidance document) generally make the issuance of standard Level 1 guidance documents a longer process.

In addition to the opportunity to comment on guidance documents themselves, interested persons have opportunities to provide input to FDA on topics for guidance documents. FDA publishes an annual guidance agenda, listing possible topics for future guidance document development or revision during the next year. FDA's most recent guidance agenda may be found in the Federal Register (75 FR 76011, December 7, 2010) online at <http://edocket.access.gpo.gov/2010/pdf/2010-30623.pdf>. Interested persons may submit comments on the topics on the list or comments that suggest additional topics for guidance. Interested persons also may identify issues in citizen petitions that the Agency may decide to

address by issuing a guidance document. (The procedures for filing citizen petitions are in 21 CFR 10.30.)

Requests for guidance documents also come to FDA informally. Frequently, interested persons identify issues that would benefit from guidance at advisory committee meetings, industry meetings, roundtables, and listening sessions or by contacting the appropriate FDA office. Interested persons sometimes submit a proposed draft guidance document to FDA. Submitting proposed draft guidance documents, rather than guidance topics, enables FDA to approach a guidance topic with a better understanding of the issues that interest the stakeholder. This may expedite the guidance document development process, particularly if the topic involves novel scientific issues. FDA solicits proposed draft guidance at a variety of different venues, such as trade association meetings and on the FDA Web site. Interested persons may submit proposed draft guidance documents on unsolicited topics as well.

All guidance topic suggestions and proposed draft guidance documents are taken into consideration, but resource limitations may prevent us from responding to each suggestion. In addition, resource limitations often prevent the Agency from taking action on the suggestions, as may legal constraints and policy considerations.

The Commissioner is issuing the GGP Report to the public to make the Agency's processes regarding guidance document development and issuance more transparent and to solicit public comment on the report and recommendations. The Agency looks forward to engaging with its stakeholders as it continues to seek opportunities to enhance the efficiency and transparency of the guidance document development process.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the GGP Report at either <http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM285124.pdf> or <http://www.regulations.gov>.

Dated: December 27, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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